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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,554	03/03/2000	Jacob Vroman	AIMPORT.011A	7420

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,554	VROMAN, JACOB	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-32 and 36-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-32 and 36-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment and Applicant's Arguments/Remarks filed 03/22/04 and 10/07/04, the Change in Power of Attorney notice filed 06/15/04 and the Change of Address filed 12/28/04 is acknowledged.

The previous Office Action filed 12/18/03 has been withdrawn. The following are the new grounds of rejection:

Claims 23-32 and 36-45 are pending. Claims 23 and 36 have been amended. Claims 1-22 and 33-35 have been cancelled. Claims 23-32 and 36-45 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-32 and 36-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 23 recites a method of providing for the *"removal" and "prevention" of wrinkles*. The specification is not

enabled for the claim limitations of 'removal and prevention of wrinkles'. While, the instant method and composition may possibly decrease or alleviate the appearance of wrinkles, it is unclear how the instant method and composition would completely 'remove' or 'prevent' wrinkles, since the removal or prevention of wrinkles would imply a cure. To date, there is no known method or composition for the complete removal or prevention of wrinkles. Thus, Applicant's specification, while being enabling for the treatment of UV protection or possible collagen stimulation, is not enabling for the 'removal' and 'prevention' of wrinkles.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation in an attempt to determine how to (1) remove wrinkles and (2) how to prevent wrinkles.

(1) The nature of the invention:

The nature of the invention is directed to a method of providing one or more of the following treatments of: UV protection, removal and prevention of wrinkles or stimulating collagen production in a mammal comprising topical administration of a composition comprising L-ascorbic acid, a non-aqueous carrier and an exfoliant.

(2) The state of the prior art:

The prior art teachings provide for the treatment of UV exposure using compositions comprising ascorbic acid (Vitamin C), carriers and exfoliants.

(3) The relative skill of those in the art:

The relative skill of those in the art is moderately high. The art teaches the use of enzymes as medicaments.

(4) The predictability or unpredictability of the art:

The predictability of the art is fairly high. Prior art formulations recognize ascorbic acid formulations comprising carriers and exfoliants, useful for cosmetic applications.

(5) The breadth of the claims:

The claims are very broad. The claims permit for the treatment of three distinct conditions: UV protection, removal and prevention of wrinkles and the stimulation of collagen production. It is unclear as to how the instant method utilizing one composition would resolve all three conditions, particularly the 'removal and prevention of wrinkles'.

(6) The amount of direction or guidance presented:

The specification states that the invention is useful in one or more of a variety of manners, to effect the following: UV protection, removal and prevention of wrinkles, and stimulation of collagen production, and other topical uses known in the art. However, the specification lacks a reasonable level of guidance. Applicant has not taught or defined how the invention arrives at a means for the removal and prevention of wrinkles. The prior art teaches and demonstrates the use of ascorbic acid compositions for exposure to UV light, but does not suggest the removal and prevention of wrinkles. It is unclear how the instant method achieves the additional effect of 'removing and preventing wrinkles', as the prior art does not, using the same composition as that of the prior art.

(7) The presence or absence of working examples:

The specification lacks a reasonable level of guidance for said methods and the working and/or prophetic examples indicate that many of the components of the formulation are not necessarily elements of the formulation of the present invention. Applicant states, that 'only as recited in the claims or written description, are particular components necessary components of the present invention'.

(8) The quantity of experimentation necessary:

In order to utilize the instant methods and compositions, it is the Examiner's position, that when the above factors are weighed, one skilled in the art could not practice the invention without undue experimentation in an attempt to determine how to (1) remove wrinkles and (2) how to prevent wrinkles.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-32 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siddiqui (US Pat. No. 6,146,664).

Siddiqui teaches an ascorbic acid – (Vitamin C) composition in a non-aqueous or substantially anhydrous silicone vehicle having superior stability, a high degree of bioavailability and effectiveness, for use in topical applications to reduce wrinkles, increase collagen growth and elasticity and for treating UV exposure, whereby the ascorbic acid is contained in an amount of 0.1% to 40% by weight. The composition also comprises exfoliants, such as Vitamin A in the form of retinol or its esters or acids, for example retinyl palmitate or retinoic acid (see Abstract); (column 2, line 45 – col. 4, line 25); Tables and Examples. A method of improving skin appearance using the ascorbic acid (Vitamin C) composition is also taught.

According to Siddiqui, the solid ascorbic acid is substantially completely insoluble in the silicone-based vehicle, and the vehicle provides an ideal reservoir for delivering the ascorbic acid into the skin where it is soluble in the moisture-laden levels of the skin. It has been unexpectedly found that the combination of the solid ascorbic acid dispersed in the silicone-based vehicle delivers the intended effect on the skin while simultaneously being safe and effective (col. 2, lines 48-60).

Siddiqui teaches that the particulate ascorbic acid consists essentially of solid ascorbic acid particles having a particle size of less than about 20 microns (μm), for example less than about 12 (μm) (instant claims require no greater than ~5(μm)) (col. 3, lines 52-54). The preparation also contains materials, such as other vitamins, cosmetic and herbal ingredients and/or medicaments as desired (col. 2, lines 64-67).

The examples demonstrate various preparations comprising ascorbic acid. For instance, Table 2 exemplifies a method of making the ascorbic acid preparation by combining Polysilicone 11, dimethicone, cyclomethicone, tocopheryl acetate and retinyl palmitate whereby solids of ascorbic acid are dispersed into this mixture with appropriate agitation. The ascorbic acid is ground into the mixture using a three-roll mill to obtain a solids ascorbic acid particle size of less than 12.5 microns. Example 6 at columns bridging 6-7 demonstrate the testing of a product for antioxidant activity using ultraviolet light. Siddiqui teaches at col. 7, lines 6-8, that the exposure of the skin to ultraviolet (UV) light is known to generate free radicals in skin cells. Various endpoints were used to measure the antioxidant activity. The data from these endpoints were compared to a negative control (cell cultures exposed to UV light without presence of antioxidants) and a positive control (cell cultures not exposed to UV light). The results clearly indicated that the ascorbic acid formulation exhibits antioxidant activity. Alternative procedures are also disclosed.

The similarities to the process of making the prior art's composition and the claimed invention is noted in that the instant application teaches that the L-ascorbic acid powder is particulate and can be prepared by grinding, etc., in the absence of any teachings for positive steps to alter the pH of the solid ascorbic acid (see pg. 4, lines 6+ of the instant application).

Note that Siddiqui uses ascorbic acid as Vitamin C (Abstract and column 1, lines 6 and 13). As such, the ascorbic acid taught by Siddiqui is L-ascorbic acid.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide UV protection or treat wrinkles or to stimulate collagen production in a mammal by topically applying a Vitamin C composition of Siddiqui having at least 30% L-ascorbic acid, by weight, and a non-aqeous carrier, since Siddiqui discloses that his formulation that contains 0.1% to 40% or higher has been found to have a high degree of bioavailability and effectiveness as a topical application with the expectation of successful treatment or therapy, as similarly desired by the applicants. Furthermore, the reference appears to teach that these benefits and effective concentrations for topical applications are well known for Vitamin C formulations (see cols. 1 & 2). The reference discloses that challenges have been how to formulate stable topical formulations of Vitamin C, particularly at the higher concentrations needed for maximum activity (col. 2, lines 15-20). Hence, the instant invention is rendered obvious and unpatentable over the teachings of Siddiqui.

Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siddiqui (US Pat. No. 6,146,664) in view of Ozlen (US Pat. No. 5,441,740).

The teachings of Siddiqui ('664) are delineated above. Siddiqui teaches exfoliants such as Vitamin A in the form of retinol or its esters or acids, for example retinyl palmitate or retinoic acid (see col. 4, lines 3-7). Siddiqui do not teach an enzymatic exfoliant, such as papain.

Ozlen ('740) teaches topical cosmetic compositions and methods of treating and alleviating skin conditions, such as skin slackness, wrinkles and dry skin comprising hydroxy acids, salicylic acid and digestive enzymes comprising a mixture of bromelain and *papain* derived from fruit extracts. The papain and bromelain digestive enzymes work synergistically to gently lift and remove older, upper layers of skin, revealing the fresher, younger skin cells beneath. The bromelain and papain digest the proteins in skin cells refining coarse, thickened skin for a smoother textured appearance. According to Ozlen, this dual action approach gives more *effective exfoliating results* while maintaining the mildness of the alpha hydroxy acid/salicylic acid combination. Cosmetic benefits are improved skin tone, softer, smoother skin, fading of age spots, diminished fine lines and wrinkles and a finer, improved texture and appearance attributed to the exposure of the underlying layers of the skin. In addition to the exfoliating benefits of the composition, other advantages of the product are that it does not increase sensitivity to the sun, help's increase skin elasticity and moisture retention and may help increase skin's production of natural humectant, and is suitable for all skin types (see reference col. 2, line 7 – col. 4, line 53).

Example 1 on columns 3-4 demonstrates a cosmetic formulation comprising various ingredients that include papain, hydroxy acids, retinyl palmitate (Vitamin A), antioxidants, minerals and the like.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include enzymatic exfoliants, such as the papain of Ozlen within the cosmetic formulation of Siddiqui because Ozlen teaches topically applied cosmetic compositions of hydroxy acids, enzymes (*i.e.,* papain), vitamins (*i.e.,* Vitamin A-retinyl palmitate) and antioxidants for treating

various skin conditions (*i.e.*, skin firmness, wrinkles, dry skin) whereby the enzymatic exfoliant, papain offers effective exfoliating results by lifting and removing upper layers of skin for a smoother textured appearance with no increase in sensitivity to the sun and similarly, Siddiqui teaches a cosmetic composition comprising exfoliants, such as Vitamin A (*i.e.*, retinyl palmitate), antioxidants and the like for use in topical applications to treat skin conditions, such as reducing wrinkles, increasing collagen growth and elasticity and treating UV exposure. The expected result would be an enhanced cosmetic formulation that provides greater exfoliating benefits for better skin conditions.

Claims 23-32 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hernandez *et al.* (US Pat. No. 5,843,411).

Hernandez *et al.* teach a stable composition and method of treating and/or preventing photo-aged skin, sunburn, wrinkles and related skin disorders by topically applying to affected areas of the skin, the treatment composition containing an effective amount of a compound such as ascorbic acid, derivatives of ascorbic acid and/or extracts containing ascorbic acid, in a pharmaceutically acceptable vehicle containing a substantially anhydrous base having no water added, wherein the ascorbic acid is contained in a concentration of 0.1% by weight to 95% by weight (see Abstract, column 2, lines 63-65); (col. 3, line 20 – col. 5, line 34).

According to Hernandez, the substantially anhydrous base protects the ascorbic acid, or its derivatives and/or extracts containing ascorbic acid, from degradation, instability, loss of potency and loss of color. The composition may also contain preservatives, humectants, pH buffers and carrier solvents. Certain pH buffers, such as alkaline sodium citrate and magnesium

citrate and solvents may also function as a substantially anhydrous base. The resultant mixture is a smooth feeling delivery vehicle, which delivers the ascorbic acid (or its derivatives) to the skin in an effective and stable manner (col. 3, line 55 – col. 4, line 17).

Other substantially anhydrous compositions, with no water added, may be substituted for the silicones, such as other emollients, including esters, amides, ethoxylated fats, mineral oil, petrolatum, vegetable and animal fats. Substantially anhydrous synthetic waxes, such as triglycerides and tribehin may be utilized (col. 5, lines 4-12).

Hernandez states that ascorbic acid, or its derivatives, esters of ascorbic acid, amides of ascorbic acid, L-ascorbic acid, known as Vitamin C, or other derivatives or related compounds which may supply L-ascorbic acid or its derivatives, is applied in a pharmaceutically acceptable vehicle, in a concentration of from 0.1% to 95% by weight, preferably 10-15% by weight, generally by frequent periodic application, such as by a once or twice daily application (col. 4, lines 33-47).

The examples at columns 5 & 6 demonstrate topically applied skin care products comprising ascorbic acid. Moreover, Table I shows the stability of examples of the composition, using ascorbic acid, specifically L-ascorbic acid at 10%.

The reference teaches that the ascorbic acid formulation is in a non-aqueous base or substantially anhydrous composition (col. 3, lines 60-67) containing silicones and derivatives of silicone chemistry (col. 4, lines 60 – col. 5, line 65).

Regarding the instantly claimed particle sizes, it is deemed obvious to one of ordinary skill that suitable ranges could be determined through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters.

Furthermore, the prior art teaches and recognizes that L-ascorbic acid and Vitamin C are known to be effective for prevention of UV damage to the skin and act as an anti-oxidant to counteract the skin damage ranging from transitory sunburn to permanent wrinkles from photo-aged skin (col. 1, lines 24-30), wherein Hernandez *et al.* invented a way to stabilize ascorbic acid and the derivatives having similar utilities. Hence, the instant invention is rendered obvious and unpatentable over the teachings of Hernandez *et al.*

Prior Art made of record and deemed relevant by Examiner:

Gardner US Pat. No. 5,516,517 (05/1996):

Gardner teaches a skin treatment process designed to reduce the aging process of skin comprising digestive enzymatic exfoliants of papain and vitamins, such as Vitamin A, E.

Response to Arguments

Applicant's arguments filed 03/22/04 with respect to claims 23-32 and 36-45 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

January 18, 2005

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